

CLAIMS

1. (E)-2-(5-Chlorothien-2-yl)-N-((3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl)ethanesulfonamide in substantially crystalline form.
2. The substantially crystalline form as claimed in claim 1 in the form of needle-shaped crystals.
3. The substantially crystalline form as claimed in claim 1 in the form of lath-shaped crystals.
4. The substantially crystalline form as claimed in claim 1 in the form of a mixture of needle-shaped and lath-shaped crystals.
5. The substantially crystalline form as claimed in any one of claims 1-4 wherein the melting point is greater than 160°C.
6. The substantially crystalline form as claimed in claim 1 having an X-ray powder diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer, wherein said X-ray powder diffraction pattern comprises 2 theta angles at one or more positions selected from the group consisting of 9.1-9.2 (± 0.1), 16.0-16.1 (± 0.1), 18.0-18.2 (± 0.1), and 18.3-18.4 (± 0.1) degrees.
7. The substantially crystalline form as claimed in claim 1 having an X-ray powder diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer, wherein said X-ray powder diffraction pattern comprises 2 theta angles at one or more positions selected from the group consisting of 9.21 ± 0.05 , 13.79 ± 0.05 , 16.11 ± 0.05 , 18.11 ± 0.05 , and 18.39 ± 0.05 degrees.
8. The substantially crystalline form as claimed in claim 1 having an X-ray powder diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer, wherein said X-ray powder diffraction pattern comprises 2 theta angles at one or more positions selected from the group consisting of 9.1 ± 0.1 , 16.0 ± 0.1 , 18.0 ± 0.1 , and 18.3 ± 0.1 degrees.
9. The substantially crystalline form as claimed in claim 1 for which the X-ray diffraction data are as shown in Table 2.
10. The substantially crystalline form as claimed in claim 1 for which the X-ray diffraction data are as shown in Table 4.
11. The substantially crystalline form as claimed in claim 1 for which the X-ray diffraction pattern is as shown in Figure 1.

12. The substantially crystalline form as claimed in claim 1 for which the X-ray diffraction pattern is as shown in Figure 2.

5 13. A method for the preparation of (E)-2-(5-chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in substantially crystalline form as claimed in any one of claims 1 to 12, which method comprises crystallisation of (E)-2-(5-chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide from
10 an organic solution, optionally in the presence of water.

14. A method as claimed in claim 13 wherein the organic solution selected from: an aromatic hydrocarbon, a cycloalkane, an ester, an alcohol or a ketone, or a mixture thereof.

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15. (E)-2-(5-Chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in substantially crystalline form as claimed in any of claims 1 to 12 for use in therapy.

20 16. A pharmaceutical composition comprising (E)-2-(5-chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in substantially crystalline form as claimed in any of claims 1 to 12 together with a pharmaceutical carrier and/or excipient.

25 17. Use of (E)-2-(5-chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in substantially crystalline form as claimed in any of claims 1 to 12 for the manufacture of a medicament for the treatment of a patient suffering from a condition susceptible to amelioration by a Factor Xa inhibitor.

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18. A method of treating a patient suffering from a condition susceptible to amelioration by a Factor Xa inhibitor comprising administering a therapeutically effective amount of (E)-2-(5-chlorothien-2-yl)-N-[(3S)-1-[(1S)-1-methyl-2-morpholin-4-yl-2-oxoethyl]-2-oxopyrrolidin-3-yl]ethanesulfonamide in substantially
35 crystalline form as claimed in any of claims 1 to 12.